Information Bulletin

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National Policy - Access to Government Funded Immunoglobulin Products in Australia

Document Number	IB2014_068
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Functional Sub group	Clinical/ Patient Services - Governance and Service Delivery
Summary	The Information Bulletin advises all staff who prescribe, order, dispense or treat patients with immunoglobulin products that on 5 November 2014 a new National Policy comes into effect for accessing government funded immunoglobulin products in Australia.
Replaces Doc. No.	Immunoglobulins, use of in NSW [PD2012_041]
Author Branch	Office of the Chief Health Officer
Branch contact	
Applies to	Local Health Districts, Chief Executive Governed Statutory Health Corporations, Specialty Network Governed Statutory Health Corporations, Affiliated Health Organisations, Community Health Centres, Government Medical Officers, Private Hospitals and Day Procedure Centres, Public Health Units, Public Hospitals, NSW Health Pathology, Cancer Institute (NSW)
Audience	All staff who prescribe, order, dispense or treat patients with immunoglobulin products
Distributed to	Public Health System, Divisions of General Practice, Government Medical Officers, Ministry of Health, Private Hospitals and Day Procedure Centres
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Director-General

NSW GOVERNMENT Health

INFORMATION BULLETIN

NATIONAL POLICY - ACCESS TO GOVERNMENT FUNDED IMMUNOGLOBULIN PRODUCTS IN AUSTRALIA

PURPOSE

The purpose of this Information Bulletin is to (1) rescind NSW Ministry of Health Policy Directive PD2012_041: *Immunoglobulins Use in NSW* and (2) to advise all staff who prescribe, order, dispense or treat patients with immunoglobulin products that from 5 November 2014 access to government-funded immunoglobulin is governed by a new national policy "*Access to Government Funded immunoglobulin Products in Australia".*

KEY INFORMATION

Polyclonal immunoglobulins (intravenous immunoglobulin [IVIg], subcutaneous immunoglobulin [SCIg] and normal human immunoglobulin) are used to treat a variety of neurological, haematological, immunological and a smaller number of miscellaneous conditions. Access to these products under the national blood arrangements is tightly controlled through the application of the Australian Health Ministers' Conference "*Criteria for the Clinical Use of Intravenous Immunoglobulin"* as well as certain policy requirements. The new national policy is one of a number of government-endorsed measures that have been developed and managed by the National Blood Authority at the request of the Jurisdictional Blood Committee to ensure good governance of these expensive products. The policy does not apply to specific immunoglobulins such as Rh D immunoglobulin and Tetanus immunoglobulin.

The new policy sets out the access requirements for each preparation of immunoglobulin and it clarifies the roles and responsibilities of all stakeholders involved in the management of immunoglobulin products.

The key changes that the policy provides for are:

1. **New Authorisation Request forms**. Forms that are currently used by prescribers will not be accepted by the "Authoriser" i.e. the Australian Red Cross Blood Service (the Blood Service) after 4 November 2014. The new Authorisation forms can be downloaded from the NBA website at:

   www.blood.gov.au/immunoglobulin-ig-governance-program.

It should be noted that the process of seeking Authorisation will no longer directly trigger an order (this must be placed separately through the health facility).

2. **The requirement for the prescriber to obtain *explicit* patient consent to:**

- Treatment with immunoglobulin products, in compliance with the National Safety and Quality Health Service (NSQHS) Standard 7, and the NSW Health PD 2005_406 *Consent to Medical Treatment – Patient Information*
- The collection, retention and use of their personal sensitive data, in accordance with both the Australian Privacy Principles and the NSW Privacy legislation. In NSW data is already collected to facilitate access to the products. Obtaining explicit patient consent ensures that patients are aware that their data is being collected and provided to the Blood Service.

3. **A standardised national patient treatment review process with a revised Patient Treatment Review Outcome Notification form.** Currently, patients in NSW are not supplied with immunoglobulin if they have not had specified reviews on given dates. This approach is now being standardised nationally. The Blood Service will send the form to the patient's treating medical specialist at least eight weeks prior to the patient's treatment review date. The outcomes of the review must be recorded on the form with any request for an increased dosage for the patient being supported by information about the patient's weight. The completed form should be returned to the Blood Service within a month of the patient review date. Failure to comply with this requirement will, except in extenuating circumstances, result in the patient no longer being able to access government funded immunoglobulin.
4. **Coordinated ordering and management of immunoglobulin products** to (1) improve transparency of product inventory; (2) ensure that product is provided to approved patients only;

and (3) reduce product expiry-related wastageInformation is included and includes information about:

Further information about the new national policy can be obtained from the NBA web site at:

www.blood.gov.au/immunoglobulin-ig-governance-program

Clinicians wishing to treat a medical condition with IVIg or SCIg that is not funded under “the Criteria” can order imported product from any commercial supplier of these products or access product under the Jurisdictional Direct Order Arrangement established by the National Blood Authority. In either case, the order must be placed directly with the relevant supplier and the cost of the product will have to be paid for by either the clinician’s hospital or the patient. There is no licensed intramuscular product commercially available outside the National Blood Agreement.

ATTACHMENTS

None.